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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,223	10/18/2001	George Q. Daley	13086-002001	7405
26161	7590	06/15/2004		
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			EXAMINER LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8-12

Office Action Summary**Application No.**

09/982,223

Applicant(s)

DALEY ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 16, 17, 23-29 and 33-49 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-13, 16, 17, 23-29, 33-45 and 47-49 is/are rejected.
 7) ☒ Claim(s) 46 is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.
 5) ☐ Notice of Informal Patent Application (PTO-152)
 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed March 25, 2004. Amendments were made to the claims. Specifically, claims 14, 15, 18-22 and 30-32 were cancelled, and claims 34-49 were newly added.

Claims 1-13, 16, 17, 23-29, 33-49 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed September 23, 2003, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48 and 49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This is a new rejection that is necessitated by the amendment of the claims.**

It is apparent that the specific plasmids pEYK2.1 and pEYK3.1 are required to practice the invention. As such, the specific plasmids must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it

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is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the plasmids. In the instant case, the process to generate the specific plasmids pEYK2.1 and pEYK3.1 that is disclosed in the specification does not appear to be repeatable, nor does it appear the plasmids are readily available to the public.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

- a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;
- c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request for the enforceable life of the patent, whichever is longer;
- d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and
- e) the deposit will be replaced if it should ever become inviable.

Failure to make one of the preceding indications in response to this Office Action will result in the rejection being maintained in either a second Non-Final or a Final rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-13, 16, 17, 23-29, 33-45 and 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "rare cutter restriction site " in claims 1-13, 16, 17, 23-29, 33-45 and 47-49 is a relative term which renders the claim indefinite. The term "rare cutter restriction site" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is noted that the specification provides the following attempts at a definition of the term "rare cutter restriction site": (a) paragraphs 15, 27, 38, 51, 73, 86, 100, 115 and 130 indicate, "In one embodiment, one or both of the 5' and 3' LTRs further comprises at least one rare cutter restriction site (e.g., an 8-bp recognition site or larger)" as a proposed definition; (b) paragraph 170 indicates "Rare cutter restriction sites useful in the vector can include, for example, restriction sites which are at least 8 base pairs or larger. Examples of such restriction sites include, but are not limited to, a site for NotI, SfiI, PacI and P1-SceI." However, these definitions are themselves indefinite because they do not define the metes and bounds of the term. The use of the terms "for example" or "e.g." in the aforementioned paragraphs merely indicate some species that are included within the broad term "rare cutter restriction site" and do not reasonably apprise the skilled artisan of what is included and excluded by the term. Because the skilled artisan cannot reasonably ascertain what other types of restriction sites would or would not be considered "rare cutters" by the aforementioned definitions (i.e., it is unclear if 6 or 7 base pair cutters are also "rare cutters"), the term "rare cutter restriction site" makes the indicated claims indefinite. **This is a new rejection that is necessitated by amendment.**

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Claim 26 (and dependent claim 34) is dependent on itself, therefore it is unclear what additional limitations are encompassed by the claim. There is insufficient antecedent basis for this limitation in the claim. **This is a new rejection that is necessitated by amendment.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13, 16, 17, 23, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Bender (as cited in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action, and as supplemented by the sequences referred to in the response to Applicant's amendment.**

This rejection is maintained in view of the sequence of pLNL6, which is used by Bender in the applied reference. The rejection is also maintained in view of the indefinite nature of the newly added limitation "rare cutter restriction site" as set forth in the rejections under 35 USC 112, second paragraph, which does not exclude restriction sites that are recognized as 6 or 7-base pair cutters; as such, the limitation will be interpreted broadly to include 6-bp and 7-bp cutters in the absence of a concise definition of "rare cutter restriction site." As shown in the sequence (available at http://seq.yeastgenome.org/vectordb/vector_descrip/LNL6.html), the 3'LTR of

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MLV contains a proviral recovery sequence which contains at least one rare cutter restriction site, such as *Tth111I* (a 9-bp cutter, which cuts once at position 470), as well as several 7-bp cutters such as *BbvCI* and *DraII*. The existence of these sites in the sequence is evidenced by the printout of the results obtained by entering said sequence into a restriction site map program, provided by Restriction Mapper (<http://www.restrictionmapper.org/>). Because the sequence of pLNL6 is inherent to the disclosure of Bender, this rejection is maintained even in view of the amendments to the claims.

Claims 1-5, 7, 11-13, 16, 17 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Kingsman (as cited in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action, and as supplemented by the sequences referred to in the response to Applicant's traversal.**

This rejection is maintained in view of the sequence of pLNL6, which makes use of the MLV 3'LTR sequence (which is contemplated for use by Kingsman; see for example column 4, lines 33-48). The rejection is also maintained in view of the indefinite nature of the newly added limitation "rare cutter restriction site" as set forth in the rejections under 35 USC 112, second paragraph, which does not exclude restriction sites that are recognized as 6 or 7-base pair cutters; as such, the limitation will be interpreted broadly to include 6-bp and 7-bp cutters in the absence of a concise definition of "rare cutter restriction site." As shown in the sequence (available at http://seq.yeastgenome.org/vectordb/vector_descrip/LNL6.html), the 3'LTR of MLV contains a proviral recovery sequence which contains at least one rare cutter restriction site, such as *Tth111I* (a 9-bp cutter, which cuts once at position 470), as well as several 7-bp cutters such as *BbvCI* and

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DraII. The existence of these sites in the sequence is evidenced by the printout of the results obtained by entering said sequence into a restriction site map program, provided by Restriction Mapper (<http://www.restrictionmapper.org/>). Because the sequence of an MLV 3' LTR (e.g., the sequence present in pLNL6) is inherent to the disclosure of Kingsman, this rejection is maintained even in view of the amendments to the claims.

Response to Arguments Concerning Claim Rejections - 35 USC § 102

Applicant's arguments filed March 25, 2004 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal: it is asserted that the teachings of Bender and Kingsman both fail to teach the presence of a 3' LTR that comprises a proviral recovery sequence selected from the group consisting of at least one recombinase site, at least one rare cutter restriction site and combinations thereof.

Applicant's arguments are not found convincing because the actual sequence of the 3'LTR of MLV (as set forth above in the supplemental portion of the rejections) contains elements that are interpreted as equivalent to the limitation "at least one rare cutter restriction site." This 3'LTR is used in the LNL6 vector used by Bender (see for example Figure 1), and portions of the MLV viral sequence (including the 3' LTR) are contemplated for use in the viral vector taught by Kingsman. As such, it is clear that the limitations of the claims as amended are still met by the previously applied references, thus Applicant's arguments are insufficient to traverse the rejection.

Allowable Subject Matter

No claims are allowable.

Claim 46 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
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JAMES KETTER
PRIMARY EXAMINER